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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/018,470	11/21/2002	Claire Marie Fraser	CHIR-0319	2853

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Chiron Corporation  
Intellectual Property R440  
PO Box 8097  
Emeryville, CA 94662-8097

EXAMINER
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NEGIN, RUSSELL SCOTT

ART UNIT	PAPER NUMBER
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1631

MAIL DATE	DELIVERY MODE
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10/19/2010

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/018,470	<b>Applicant(s)</b> FRASER ET AL.	
	<b>Examiner</b> Russell S. Negin	<b>Art Unit</b> 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 11 August 2010.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,2,4,26 and 83-85 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,4,26 and 83-85 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Comments***

Applicant's amendments and request for reconsideration in the communication filed on 11 August 2010 are acknowledged and the amendments are entered.

Claims 1, 2, 4, 26 and 83-85 are pending in the instant application.

Claims 1, 2, 4, 26 and 83-85 are examined in this Office action.

### ***Claim Rejections - 35 USC § 112***

The following rejection is reiterated:

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 85 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 85 recites that the open reading frame does not consist of one or more of NMB0427, NMB0428, NMB0429, and NMB0430, and Appendix B sufficiently describes each of the NCBI numbers. However, since no exact sequences (i.e. with SEQ ID NOs) are given, and since NMB0427, NMB0428, NMB0429, and NMB0430 are NCBI identification numbers, this claim is indefinite because the sequence content and corresponding organisms may be changed in GenBank as a function of time. In other words, the sequence contents in the GenBank database corresponding to NMB0427,

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NMB0428, NMB0429, and NMB0430 at the time of filing may not be the same currently as the content that existed at the time of filing.

Response to arguments:

Applicant's arguments filed 11 August 2010 have been fully considered but they are not persuasive.

Applicant argues that using the NMB number to label a sequence along with an additional convention for annotating open reading frames, one of skill in the art is capable of deducing any potential future changes in this sequence in the NCBI database corresponding to the above mentioned NMB number. This argument is not persuasive because since applicant admits the sequence corresponding to the NMB number may change, it is unclear at the time of filing the intent of applicant when annotating these sequences. One of skill in the art should not have to deduce (using post-filing art) the location and content of the open reading frame based on inconsistencies between the original sequence recited using an NMB number and any changes in this original sequence corresponding to this same NMB number involving post art. Consequently, since claim 85 does not recite a clear and "static" version of the sequence with the NMB number, the claim is indefinite as to the sequence recited.

***Claim Rejections - 35 USC § 103***

The following rejection is reiterated:

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-2, 4, 26, and 83-85 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kraus et al. [US Patent 5,183,884; issued 2 February 1993; filed 1 December 1989] as evidenced by the Definition of ORF [Glossary, obtained online from [representinggenes.org](http://representinggenes.org) on 6 May 2010].

The claims are drawn to a method for identifying an amino acid sequence from the *N. meningitidis* serogroup B strain MC58 genome of SEQ ID NO:1. This method comprises the step of providing a computer database comprising the SEQ ID NO:1. The method also comprises searching for putative open reading frames or protein-coding sequence within the computer database. The method also comprises identifying an amino acid sequence corresponding to the searched putative open reading frame or

protein coding sequences. The method also comprises outputting the identified amino acid sequence to a user display or storing the identified amino acid sequence to a computer readable media. The method also comprises producing a protein comprising the identified amino acid sequence.

Claim 2 further comprises searching within SEQ ID NO:1 contained in the computer database for an initiation codon; and searching for an in-frame termination codon downstream of the initiation codon.

Claim 4 and 26 are further limiting for identifying the protein by producing an antibody which binds to the protein, and determining whether the antibody recognizes this produced protein.

Claim 83 is further limiting comprising outputting the identified amino acid sequence to a user display.

Claim 84 is further limiting comprising storing the identified amino acid sequence to a computer storage medium.

Claim 85 is further limiting wherein the putative open reading frame does not consist of one or more of NMB0427, NMB0428, NMB0429, and NMB0430.

The document of Kraus et al. teaches a DNA segment encoding a gene for a receptor related to the epidermal growth factor receptor [title]. Specifically, Figures 3 and 4 of Kraus et al. illustrate a database of a sequence comprising a nucleic acid sequence. Figures 3 and 4 of Kraus et al. also illustrate the corresponding amino acid sequences alongside the DNA sequence. Figures 3 and 4 themselves function as user displays for the database of sequences. Column 3, line 64 to column 4, line 10 of Kraus

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et al. teaches that the sequences were analyzed (i.e. searched) and resulted in the presence of a plurality of open reading frames corresponding to epidermal growth factors of interest. As defined in the "Glossary," each open reading frame (or ORF) is characterized by "a DNA sequence starting with a start codon and ending with a stop codon, and therefore potentially signals a coding sequence that is translated into a functional product RNA or polypeptide." Consequently, by searching for the ORFs within the sequence of Kraus et al., one of skill in the art requires the searching of both the initiation and termination codons of each ORF.

Claim 4 of Kraus et al. teaches the use of antibodies in the process of recognizing the appropriate epidermal growth factor. Syntheses of the proteins in Kraus et al. (including translated peptides and antibodies) are described in column 8, lines 9-31 of Kraus et al.

Column 12, lines 34-54 of Kraus et al. teach the computer limitations of the instant set of claims. Specifically, biological sequence analysis was assisted by use of computer readable media (IntelliGenetics software) and the hardware of the NCI Advanced Scientific Computing Laboratory.

Since the open reading frames in Kraus et al. correspond to epidermal growth factors (column 3, line 64 to column 4, line 10), they do not contain one or more of NMB0427, NMB0428, NMB0429, and NMB0430.

It is noted that the method of Kraus et al. differs from the claimed invention only in the content of the nucleic acid sequence which is stored and/or displayed in the computer system and produced. The MPEP states in section 2106 subsection VI:

**VI. DETERMINE WHETHER THE CLAIMED INVENTION COMPLIES WITH 35 U.S.C. 102 AND 103**

Reviewing a claimed invention for compliance with 35 U.S.C. 102 and 103 begins with a comparison of the claimed subject matter to what is known in the prior art. See MPEP § 2131 - § 2146 for specific guidance on patentability determinations under 35 U.S.C. § 102 and 103. If no differences are found between the claimed invention and the prior art, then the claimed invention lacks novelty and is to be rejected by USPTO personnel under 35 U.S.C. 102. Once differences are identified between the claimed invention and the prior art, those differences must be assessed and resolved in light of the knowledge possessed by a person of ordinary skill in the art. Against this backdrop, one must determine whether the invention would have been obvious at the time the invention was made. If not, the claimed invention satisfies 35 U.S.C. 103.

The MPEP further states in section 2106.01:

When nonfunctional descriptive material is recorded on some computer-readable medium, in a computer or on an electromagnetic carrier signal, it is not statutory and should be rejected under 35 U.S.C. 101. In addition, USPTO personnel should inquire whether there should be a rejection under 35 U.S.C. 102 or 103. USPTO personnel should determine whether the claimed nonfunctional descriptive material be given patentable weight. USPTO personnel must consider all claim limitations when determining patentability of an invention over the prior art. *In re Gulack*, 703 F.2d 1381, 1385, 217 USPQ 401, 403-04 (Fed. Cir. 1983). USPTO personnel may not disregard claim limitations comprised of printed matter. See *Gulack*, 703 F.2d at 1384, 217 USPQ at 403; see also *Diehr*, 450 U.S. at 191, 209 USPQ at 10. However, USPTO personnel need not give patentable weight to printed matter absent a new and unobvious functional relationship between the printed matter and the substrate. See *Lowry*, 32 F.3d 1583-84, 32 USPQ2d 1035; *In re Ngai*, 367 F.3d 1336, 70 USPQ2d 1862 (Fed. Cir. 2004).

The difference between the method of Kraus et al. and the claimed invention (i.e. the sequence of SEQ ID NO: 1) constituted non-functional descriptive material because the content of the nucleic acid sequence does not alter how the method functions (i.e. changing the content of the nucleic acid sequence does not cause the method to perform a different function than the method taught in Kraus et al.). *In re Gulack*, 217 USPQ 401 (Fed. Cir. 1983) teaches that printed matter (i.e. in this application sequences such as SEQ ID NO: 1) that is not functionally related to the structure of the invention does not distinguish the invention from prior art in terms of patentability.

Response to arguments:



Applicant's arguments filed 11 August 2010 have been fully considered but they are not persuasive.

Applicant argues against the instant rejection in the instant Office action using previous statements from the prosecution history of the application and prior Office actions regarding non-functional descriptive material and section 2106 of the MPEP. Applicant is advised that the statements in the instant Office action and the current version of section 2106 of MPEP are the valid statements from which to follow.

Applicant additionally argues that Kraus et al. teaches expression of a protein unrelated to the *Neisserial* gene. This argument is not persuasive because in this OBVIOUSNESS (not anticipatory) prior art rejection, the *Neisserial* gene acts as non-functional descriptive material. In other words, using (and producing) an entirely different gene than SEQ ID NO: 1 from *N. meningitidis* is an obvious variant of the claimed subject matter because the content of SEQ ID NO: 1 has no relation to the function of the claims. For example, *in silico* searching the gene for ORFs, *in silico* identifying amino acids corresponding to the genes in the ORFs, *in silico* outputting this resulting amino acid sequence, and producing the resultant protein can be analogously accomplished on any gene with an ORF as an obvious variant of the same process on SEQ ID NO: 1.

### **Conclusion**

No claim is allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the central PTO Fax Center. The faxing of such pages must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The Central PTO Fax Center Number is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Russell Negin, whose telephone number is (571) 272-1083. The examiner can normally be reached on Monday-Friday from 8:30 am to 5:30 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisor, Marjorie Moran, Supervisory Patent Examiner, can be reached at (571) 272-0720.

Information regarding the status of the application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information on the PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Russell S. Negin/  
Examiner, Art Unit 1631  
18 October 2010